

REMARKS

Claims 16-36 are currently pending in the present application. Claims 34-36 stand withdrawn from consideration by the Examiner as being directed to a non-elected invention.

Applicants wish to extend their appreciation to Examiner Mi for withdrawing the rejection of claims 16-18, 32 and 33 under 35 U.S.C. § 102(b) in response to the Pre-Appeal Brief Request for Review filed on September 11, 2008.

The rejection of claims 16-33 under 35 U.S.C. § 103(a) as being obvious over Noble (U.S. Patent 5,484,611) in view of McCleary (U.S. 2002/0182196) and Bydlon (U.S. 2003/0050341) is respectfully traversed.

Claim 16 is directed to a composition comprising the following two separate and distinct components: (1) a phospholipid having an n-3 polyunsaturated fatty acid constituent selected from the group consisting of docosahexaenoic acid, docosapentaenoic acid and eicosapentaenoic acid; and (2) α -linolenic acid and/or an oil comprising α -linolenic acid. Noble, McCleary and Bydlon, when considered alone or in combination, fail to disclose or suggest the claimed composition. Even if sufficient motivation and guidance is considered to have been provided by Noble, McCleary and/or Bydlon to arrive at the claimed composition, which is clearly not the case, such a case of obviousness is rebutted by a showing of superior properties and secondary considerations. As shown by the comparative experimental data presented in Table 1 of the present specification, the composition in accordance with the present invention remarkably exhibited superior properties with respect to enhanced systemic absorption of n-3 polyunsaturated acids into blood and tissue, as compared to the inferior properties exhibited by the conventional composition.

Claim 16 is directed to a composition comprising the following two separate and distinct components: (1) a phospholipid having an n-3 polyunsaturated fatty acid constituent selected from the group consisting of docosahexaenoic acid (DHA), docosapentaenoic acid and eicosapentaenoic acid; and (2) α -linolenic acid and/or an oil comprising α -linolenic acid.

Noble describes a fatty acid composition comprising a mixture of phosphatidyl serine, phosphatidyl choline and phosphatidyl inositol phospholipids having DHA and 18:3(n-3) linolenic acid (a.k.a., α -linolenic acid) as fatty acid constituents thereof (See e.g., column 1, lines 45-52, column 2, lines 12-17 and 25-30, column 3, Table 1 and lines 24-65, and claims 1 and 9). Since the α -linolenic acid is a fatty acid constituent of the phospholipid, Noble fails to describe the claimed composition comprising the following two separate and distinct components: (1) a phospholipid having an n-3 polyunsaturated fatty acid constituent selected from the group consisting of DHA, docosapentaenoic acid and eicosapentaenoic acid; and (2) α -linolenic acid and/or an oil comprising α -linolenic acid.

McCleary describes a composition for normalizing impaired or deteriorating neurological function which may comprise: phosphatidyl serine; DHA; and γ -linolenic acid (GLA) (See e.g., abstract, [0131] and [0177]). McCleary fails to describe that the DHA is a fatty acid constituent of the phospholipid. In addition, the alpha-linolenic acid of the claimed composition is fundamentally different from the gamma-linolenic acid described in McCleary. Therefore, McCleary fails to describe the claimed composition comprising: (1) a phospholipid having an n-3 polyunsaturated fatty acid constituent selected from the group consisting of DHA, docosapentaenoic acid and eicosapentaenoic acid; and (2) α -linolenic acid and/or an oil comprising α -linolenic acid. As a result, McCleary fails to compensate for the above-mentioned deficiencies of Noble.

Bydlon describes a composition comprising DHA, which is useful for treating the central nervous system, preventing Alzheimer disease and dementia in the elderly, preventing heart disease and lowering the level of undesirable triglycerides in the blood (See e.g., [0008]). Bydlon describes that DHA may be obtained from a plethora of various natural oils including, but not limited to, flaxseed oil (a.k.a., linseed oil), canola oil (a.k.a., rapeseed oil), vegetable oil, safflower oil, sunflower oil, nasturtium seed oil, mustard seed oil, olive oil, sesame oil, soybean oil, corn oil, peanut oil, cottonseed oil, rice bran oil, babassu nut oil, palm oil, low erucic rapeseed oil, palm

kernel oil, fish oil and marinol oil (See e.g., [0024], [0025]). Bydlon describes that the natural oils themselves may be incorporated into the composition as a source of DHA because these oils, especially fish oil and marinol oil, often contain DHA in concentrated amounts thereby providing desirable DHA levels in the composition (See e.g., [0025]). Bydlon describes that fish convert linolenic acid, obtained from ingesting algae, to DHA (See e.g., [0024]).

Although Bydlon describes that fish convert linolenic acid to DHA, *the phospholipid of Noble having DHA as an n-3 polyunsaturated fatty acid constituent thereof cannot be formed from the linolenic acid of Bydlon*. Moreover, while Bydlon describes that the natural oils are used as *sources of DHA*, Bydlon fails to disclose or suggest using the natural oils as *sources of α -linolenic acid*. Bydlon also fails to disclose *which of the various natural oils described therein actually contain α -linolenic acid*. Therefore, Bydlon fails to provide a skilled artisan with sufficient motivation and guidance to *particularly select specific natural oils that contain α -linolenic acid* from either the tremendously large genus of natural oils, or the preferred natural oils, described therein. Since Bydlon fails to describe incorporating α -linolenic acid into the composition, Bydlon fails to compensate for the above-mentioned deficiencies of Noble.

Applicants respectfully submit that a skilled artisan would not have been motivated to use a specific natural oil described in Bydlon as a source of α -linolenic acid for incorporation into the composition of Noble to arrive at the claimed composition absent *impermissible hindsight reconstruction*.

Noble, McCleary and Bydlon, when considered alone or in combination, clearly fail to disclose or suggest the claimed composition comprising: (1) a phospholipid having an n-3 polyunsaturated fatty acid constituent selected from the group consisting of DHA, docosapentaenoic acid and eicosapentaenoic acid; and (2) α -linolenic acid and/or an oil comprising α -linolenic acid. As a result, Noble, McCleary and/or Bydlon fail to anticipate or render obvious the claimed invention.

Assuming *arguendo* that sufficient motivation and guidance is considered to have been provided by Noble, McCleary and/or Bydlon to arrive at the presently claimed composition, which is clearly not the case, such a case of obviousness is rebutted by a showing of superior properties and secondary considerations.

As discussed in the present specification, conventional compositions comprising n-3 polyunsaturated acids, such as DHA, docosapentaenoic acid and eicosapentaenoic acid, suffer from inferior properties with respect to systemic absorption into blood and tissue (See e.g., page 1, lines 10-25, and page 2, lines 1-4). Accordingly, there has been a long-felt need to provide a composition that exhibits superior properties with respect to enhanced systemic absorption of n-3 polyunsaturated acids into blood and tissue. Based on the limited disclosures of Noble, McCleary and Bydlon, other skilled artisans have failed to discover a solution to this long-felt need.

As repeatedly stated during prosecution of the present application and as shown by the comparative experimental data presented in Table 1 of the present specification, which is reproduced hereinbelow for the Examiner's convenience, Applicants have discovered that superior properties with respect to remarkably enhanced systemic absorption of n-3 polyunsaturated acids into blood and tissue are exhibited by the composition of the present invention.

Table 1

Test Group	DHA content (%) in all fatty acids: n = 5	
	PS-DHA + linoleic acid (safflower oil)	PS-DHA + α -linolenic acid (linseed oil)
Serum	4.24 \pm 0.10	6.60 \pm 0.23
Brain	5.20 \pm 0.17	6.03 \pm 0.12

Specifically a composition comprising (1) a phospholipid having an n-3 polyunsaturated fatty acid constituent selected from the group consisting of DHA, docosapentaenoic acid and eicosapentaenoic acid and (2) an oil (e.g., linseed/flaxseed oil) comprising α -linolenic acid, in accordance with the present invention, exhibited superior properties with respect to remarkably enhanced systemic absorption of an n-3 polyunsaturated acid (e.g., DHA) into blood serum and

tissue (e.g., brain), as compared to the inferior properties exhibited by conventional compositions, which do not contain (1) a phospholipid having an n-3 polyunsaturated fatty acid constituent selected from the group consisting of DHA, docosapentaenoic acid and eicosapentaenoic acid; and (2) α -linolenic acid and/or an oil comprising α -linolenic acid, as separate and distinct components, in accordance with the composition of the present invention.

This evidence clearly demonstrates that a composition in accordance with the present invention remarkably exhibits superior properties with respect to enhanced systemic absorption of n-3 polyunsaturated acids into blood and tissue, as compared to the inferior properties exhibited by conventional compositions, which comprise: (1) a phospholipid having DHA as an n-3 polyunsaturated fatty acid constituent thereof; and (2) an oil comprising *linoleic acid* (not to be confused with the claimed α -linolenic acid), such as the safflower oil described in Bydlon.

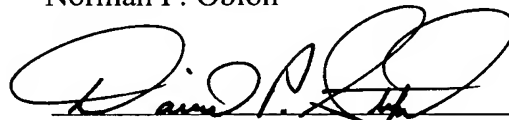
Withdrawal of this ground of rejection is respectfully requested.

The Examiner is respectfully reminded that upon a determination that the product claims drawn to the elected invention are found allowable, method claims drawn to the non-elected invention should be rejoined and examined for patentability, pursuant to MPEP § 821.04 and *In re Ochiai*, 71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995).

In conclusion, Applicants submit that the present application is now in condition for allowance and notification to this effect is earnestly solicited.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.
Norman F. Oblon



David P. Stitzel
Attorney of Record
Registration No. 44,360

Customer Number
22850

Tel: (703) 413-3000
Fax: (703) 413 -2220
(OSMMN 06/04)